

IN THE UNITED STATES DISTRICT COURT FOR THE  
MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the )  
Use and Benefit of Herself and the Next Kin of )  
Richard Smith, Deceased, )  
 )  
Plaintiff, ) Civil No. 3:05-0444  
 ) Judge Aleta A. Trauger  
v. ) (Dist. Of MA No.  
 ) 1:05-cv-11515PBS)  
PFIZER, INC., *et al.*, )  
 )  
Defendants. )

**DECLARATION OF MARK S. CHEFFO IN SUPPORT OF  
DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO  
EXCLUDE THE TESTIMONY OF SHEILA WEISS SMITH, PH.D.**

I, Mark S. Cheffo, declare and state as follows:

1. I am a partner with the law firm of Skadden, Arps, Slate, Meagher & Flom LLP, attorneys for Defendants Pfizer Inc and Warner-Lambert Company LLC. I make this declaration based on my own personal knowledge and information.
2. Attached as Exhibit A is a true and correct copy of the expert report of Sheila Weiss Smith, Ph.D., dated November 4, 2008.
3. Attached as Exhibit B is a true and correct copy of the Curriculum Vitae of Sheila Weiss Smith, Ph.D.
4. Attached as Exhibit C is a true and correct copy of the Expert Report of Sheila Weiss, Ph.D., dated December 20, 2007.
5. Attached as Exhibit D is a true and correct copy of excerpts from the deposition of Sheila Weiss Smith, Ph.D., dated December 22, 2008.
6. Attached as Exhibit E is a true and correct copy of a letter from Dr. Russell Katz, FDA to Manini Patel, Director of Worldwide Regulatory Affairs, Pfizer; Bates No. NRE0009216746.

7. Attached as Exhibit F is a true and correct copy of the FDA Statistical Review and Evaluation, Anti-Epileptic Drugs and Suicidality dated May 23, 2008.

8. Attached as Exhibit G is a true and correct copy of excerpts of the transcript from the July 10, 2008, FDA Advisory Committee meeting on antiepileptic drugs and suicidality.

9. Attached as Exhibit H is a true and correct copy of FDA's "Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment," March 2005.

10. Attached as Exhibit I is a true and correct copy of an email from Michael Wasicko, counsel for Defendants, to Keith Altman, counsel for Plaintiff dated February 2, 2009.

11. Attached as Exhibit J is a true and correct copy of excerpts from the deposition of Cheryl Blume, Ph.D., dated November 22 and 23, 2007.

I declare the foregoing statements are true and correct under the penalties of perjury, this the 27<sup>th</sup> day of April, 2010.



Mark S. Cheffo

**CERTIFICATE OF SERVICE**

I hereby certify that on this the 27<sup>th</sup> day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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/s/ Gerald D. Neenan